

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Schaller et. al.

Examiner: Nihir. B. Patel

Serial No.: 09/828,322

Group Art Unit: 3772

Filing Date: April 5, 2001

Docket No.: P0021814.00

Title: BRIDGE CLIP TISSUE CONNECTOR APPARATUS AND METHODS

**MAIL STOP AF**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Sir:

In response to the Final Office Action dated February 17, 2009, Applicants request a pre-appeal brief review because of clear errors in the Examiner's rejections. This paper is being filed together with a Notice of Appeal.

**Rejection under 35 U.S.C. §112, first paragraph**

Claims 1-19, 39 and 40 were rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. In rejecting claims 1-19 and 39-40, under 35 U.S.C. §112, first paragraph, the Examiner maintains the contention made in the previous Office Action, that the subject matter "at least one of the two clips is a self closing clip" was not described in the specification. Applicants disagree. Applicants have clearly disclosed the subject matter in question. For example, at page 6, lines 11-12 Applicants disclose, "a surgical fastener having two clips, **at least one of which is self-closing**". In addition, and as noted in the Amendment and Response dated August 28, 2008, claims 5 and 20 as filed recite the language in question. Applicants further submit that the Examiner failed to respond to Applicants reply regarding the 35 U.S.C. §112 rejection. According to the examination guidelines at M.P.E.P. §2163III.b., **"Upon reply by applicant, before repeating any rejection under 35 U.S.C. 112, para. 1, for lack of written description, review the basis for the rejection in view of the record as a whole, including amendments, arguments, and any evidence submitted by applicant...fully respond to applicant's rebuttal arguments, and properly treat any further showings submitted by applicant in the reply"**. No response by the Examiner regarding Applicants' arguments was presented in the February 17, 2009 Office Action and the rejection, in error, was repeated in the Final Office Action for which this Pre-Appeal Request seeks Review.

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Filing Date: July 29, 2002  
Title: TISSUE CONNECTOR APPARATUS AND METHODS

Dkt.: P-21544.01

Rejection under 35 U.S.C. §102(b) – Sander

Claims 1-6, 20, 24-26, 39-43, 47, 48-50, 54 and 55 were rejected under 35 U.S.C. §102(b) as being anticipated by Sander U.S. Patent No. 5,374,268 (“Sander”). The Examiner generally characterizes Sander as teaching a “self-closing” clip by referring to the phrase “as the **needles** are pushed through the meniscus to draw the edges of the tear together” (Sander, col. 4, lines 60-67). The Examiner posits that this phrase “implies that inherently the clips are self closing as they are drawing the edges of the tear together”. (Final Office Action p. 3 ¶6). Applicants respectfully disagree and submit that the Examiner’s position is clearly in error. At the outset, the Examiner identifies anchor members 14 of Sander as being the claimed clips. Sander discloses *needles* 12 which are separable from *anchor members* 14. For this reason, any “implication” from the cited phrase has no bearing on the claims regardless of whether the needles 12 somehow achieve a “closed” position relative to tissue. In other words, the phrase relied upon by the Examiner recites only “needles” and not anchor members (allegedly the claimed “clips”). To the extent the *anchor members* 14 are applied as the claimed “clips”, Sander does not disclose the anchor members 14 as being “self-closing”. Nor does Sander disclose the *needles* as being self-closing. The language relied upon by the Examiner, “as the needles are **pushed through**” directly contrasts the Examiner’s position and implies action by the surgeon (a pushing force) rather than a self-closing action. The term “self-closing” requires that the clip **in and of itself** accomplishes the closed configuration. In contrast, Sander discloses a straight (or curved) needle which is pushed through tissue. The needle does not in and of itself close or accomplish a position of holding tissue together. Thus since the “drawing” of tissue together with the needles 12 of Sander requires a surgeon-applied action, the needles 12 are clearly *not* “self-closing”.

**Independent claim 1** is not anticipated by and is allowable over Sander for at least the following reasons. Claim 1 recites in part that at least one of the two clips is a self-closing clip. As described in detail above, the anchor members 14 (referred to by the Examiner as being the claimed clips) are not sized and shaped to attach tissues and hold the tissues together therein, nor are they self-closing clips. Similarly, the *needles* 12 do not satisfy the language of claim 1. In addition, claim 1 recites in part that the self-closing clip is adapted to self-transition from a first shape to a second shape, the first and second shapes being different. Sander does not teach this. The Examiner posits that “the fact that when the shape of the device changes from a first shape to a second shape after being inserted implies that the shapes are different”. However, the Examiner

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fails to recognize that claim 1 provides that the change of shape occurs as a result of the claimed *self-transitioning* clips, of which Sander is devoid. Regardless of whether Sander discloses varying shapes or embodiments, the Sander device does not self-transition from a first shape to a second shape. Furthermore, although the Examiner does not apply the needles 12 as being the “clips” of claim 1, it is noted that the disclosed needles do not provide different shapes, let alone are they adapted to self-transition from a first shape to a different second shape. Applicants note that in FIG. 1, the needles 12 are straight, and in the alternative embodiment of FIG. 2, the needles 32 are curved. Sander makes abundantly clear that the embodiments of FIGS. 1 and 2 are entirely **different embodiments** rather than varying shapes of the same embodiment. In other words, the needles 12 are always straight or the needles 32 are always curved. In no instance does Sander describe the needles as self-transitioning between different shapes.

Claims 2-6 depend from claim 1 and are thus allowable. In addition, claim 3 recites in part that each of the two clips has an open configuration and a closed configuration independent of the other clip. The Examiner alleges that a position of each of the anchoring members 14 *relative to the other* constitutes open and closed configurations as claimed (the Examiner alleges that the anchor members are “open” when spread apart from each other and “closed” when closer together). In contrast, however, claim 3 provides that the clips **in and of themselves** each have an open configuration and a closed configuration. Thus, movement of anchor members 14 *relative to one another* as Sander provides has no relevancy to the language of claim 3. Claim 4 sets forth in part a bridge portion which provides a predetermined spacing between the clips. The Examiner refers to FIG. 4 of Sander and references suture 16 of Sander as being the claimed “bridge” with predetermined spacing. Applicants disagree. Because the suture 16 is flexible, the suture 16 cannot be a bridge portion providing a predetermined spacing as claimed. The spacing in FIG. 4 is dictated by the tissue within which the needles 12 are inserted and therefore is determined only upon placement within tissue. Claim 6 recites that the self-closing clip comprises shape memory material. In rejecting claim 6 the Examiner states, “the bridge portion is flexible and therefore has shape memory material”. Applicants respectfully submit that this contention is a *non sequitur* and disagree that the suture “bridge” of Sander has shape memory material. Regardless, the flexibility and alleged shape memory of the suture portion 16 is irrelevant to the language of claim 6 as claim 6 provides in part that the self-closing clip comprises shape memory material. The “bridge” of Sander has no bearing on the self-closing clip as claimed.

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**Independent Claim 20** provides in part a surgical fastener including at least one self-closing clip. As described above, anchor members 14 (allegedly the claimed "clips") are not self-closing, nor do they provide an unbiased closed configuration having a loop shape as claimed. Contrary to the Examiner's assertion, Sander's FIG. 1 does not show the combined structure of anchoring members 14 and suture 16 as having a loop shape as set forth in Applicants' claim. The combined structure of anchoring members 14 and suture 16 shown in FIG. 1 is generally U-shaped; it clearly does not have a "loop" shape in a closed configuration let alone a biased configuration having a shape differing from a shape of the closed configuration. Furthermore, claim 20 provides in part a release mechanism having a first position biasing the clip in an open configuration and a second position to unbias a clip into the closed configuration. The Examiner refers to the *suture* as being the "release mechanism" as claimed. Applicants respectfully submit that this is clearly in error. Suture 16 does not have a position that unbias the anchor members 14 (the so-called "clips") into a closed configuration having a loop shape as claimed, nor a first position that biases the anchor members 14 into an open configuration having a shape differing from a shape of the closed configuration.

**Independent claim 24** recites in part a surgical fastener including at least one self-closing clip having a loop shape terminating at a first end. As described above, the anchor members 14 of Sander are not self-closing clips, nor are needles 12 or 32. Notably, claim 24 recites that tissue piercing members are releasably coupled to ends of the claimed surgical fastener, necessitating that the needles 12 or 32 of Sander cannot be interpreted as the claimed clips. In addition, Sander does not disclose a **loop shaped** self-closing clip. The Examiner refers to FIG. 1 and alleges that "both clips are self closing when they are inserted in the tissue". As explained in detail above, and as is abundantly clear from Sander's disclosure, neither FIG. 1 to which Examiner refers, nor any other figure of Sander disclose a self-closing clip having a loop shape.

**Independent Claim 41** provides in part a tissue connector apparatus including an elongated member having first and second loop shaped portions each having a free end and being deformable into a second deformed shape self-tending to return from a second deformed shape toward the loop shape. The Examiner refers to FIGS. 2 and 6 of Sander as teaching looped and deformed shapes. The Examiner also alleges that when the shape of the Sander device "changes" from a first shape to a second shape after being inserted implies that the shapes are different. Applicants respectfully submit that the Examiner is referring not to different or changing shapes

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of a single embodiment, but rather to entirely different embodiments. As described in connection with claim 1 above, the needles 32 of FIG. 2 are not the needles 12 of FIG. 6. Therefore, while the needles 32 may be curved in FIG. 2, nothing in Sander teaches that the needles 32 deform into a different state provided by the straight needles 12 of FIG. 6. The needles of Sander are *either* curved or straight but not both.

**Independent Claim 48** discloses in part a tissue connector apparatus comprising an elongated member having a first loop shaped portion, a second loop shaped portion and a bridge portion, each loop shaped portion having the property of tending to return towards its loop shape by moving upon itself. As described above, the curved needles 32 of FIG. 2 are not deformable into a second deformed shape having the property of tending to return toward a looped shape by moving upon themselves.

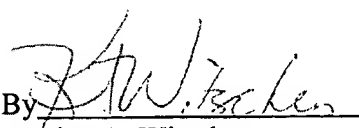
**Independent Claim 55** relates to a tissue connector apparatus having two clips, with each clip self-transitioning from an open configuration to a closed configuration. Again, as described above, anchor members 14 (the alleged "clips") do not provide both an open and closed configuration. Furthermore, the anchor members 14 do not and cannot self-transition from an open to a closed configuration.

**Rejection under 35 U.S.C. §103(a) – Sander**

Claims 44 and 51 were rejected under 35 U.S.C. §103(a) as being unpatentable over Sander (US 5,374,268). Claims 44 and 51 are dependent on independent claims 41 and 48 and are allowable at least by virtue of their dependency upon allowable claims as discussed above.

Respectfully submitted,

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